Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Tecvayli™ (teclistamab-cqyv) injection, for subcutaneous administration

Effective: July 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Multiple Myeloma (MM) is a relatively uncommon cancer accounting for approximately 1 to 2 percent of all cancers and slightly more than 17 percent of hematologic malignancies. It is more common in men than in women, and more common among individuals of African American descent. Multiple myeloma is a progressive, incurable blood cancer that affects plasma cells. Plasma cells are a type of matured B cells found in bone marrow that produce antibodies. When damaged, they rapidly displace normal cells and create tumors in the bone marrow.

Multiple myeloma (MM) is typically characterized by the neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures. Additional disease-related complications include hypercalcemia, kidney impairment, anemia, and infections.

There are many approved treatment combinations for patients with relapsed and/or refractory multiple myeloma (RRMM). Most patients experience serial relapses over time and will ultimately receive most if not all available agents at some point during their disease course. The choice of therapy for relapsed MM must consider prior therapy, response, and likelihood of the disease being sensitive or refractory to prior agents. In general, refractory disease is defined as progressing on or within 60 days of receiving standard doses of a specific therapy.

While overall outcomes for patients with MM have improved substantially in recent decades, MM is a heterogeneous disease with some patients progressing rapidly despite treatment and others responding to treatment for many years.

Food and Drug Administration (FDA) Approved Indications:

- TECVAYLI is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. Tecvayli is available as an "off-the-shelf" T cell–redirecting, bispecific antibody targeting both B-cell maturation antigen (BCMA) and cluster of differentiation 3 (CD3), and it is administered subcutaneously as a weekly treatment until disease progression.

REMS Program Requirement:

The approved label for Tecvayli includes a Boxed Warning for life-threatening or fatal Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune effector cell-associated neurotoxicity syndrome (ICANS), and the drug will only be available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), called the TECVAYLI REMS program. Notable requirements of the TECVAYLI REMS program include the following:

- Prescribers must be certified with the program by enrolling and completing training.
- Prescribers must counsel patients receiving TECVAYLI about the risk of CRS and neurologic toxicity, including ICANS, and provide patients with Patient Wallet Card.
- Pharmacies and healthcare settings that dispense TECVAYLI must be certified with the TECVAYLI REMS program and must verify prescribers are certified through the TECVAYLI REMS program.
- Wholesalers and distributers must only distribute TECVAYLI to certified pharmacies or healthcare settings.

Further information about the TECVAYLI REMS program is available at www.TECVAYLIREMS.com or by telephone at 1-855-810-8064.

Note: Due to the risk of CRS and neurologic toxicity, including ICANS, hospitalization is required during administration of the first three (3) doses of Tecvayli. Tecvayli is given in a step-up titration regimen, which includes step-up dose 1 (Day 1), step-up dose 2 (Day 4), and then the first treatment dose (Day 7), all of which must be done in a hospital setting for 48 hours. Authorization for inpatient hospitalizations must be requested separately through Precert review. After the initial three (3) doses, Tecvayli may be administered in an outpatient setting by a healthcare provider.

Clinical Guideline Coverage Criteria

The Plan may cover Tecvayli (teclistamab-cqyv) when all the following clinical criteria is met:

1. The Member has a confirmed diagnosis of relapsed or refractory multiple myeloma (RRMM) and has already received at least four (4) prior lines of therapy, including:
    a. A proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib]).
    b. an immunomodulatory agent (e.g. Thalomid [thalidomide], Revlimid [lenalidomide] or Pomalyst [pomalidomide])
    c. an anti-CD38 monoclonal antibody (e.g., Darzalex, Darzalex Faspro [daratumumab], Sarclisa [isatuximab])

AND

2. The Member is 18 years of age or older

AND

3. The Member has an Eastern Cooperative Oncology Group (ECOG) score of 0 to 2

AND

4. The Member will only receive Tecvayli therapy as a single agent regimen

Limitations

- The Plan may authorize Tecvayli therapy for up to 12 months if Clinical Guideline Coverage Criteria is met.
- The first three step-up titration doses of Tecvayli require inpatient hospitalization for up to 48 hours after administration. Inpatient hospital stays must be approved separately through Precert review.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9380	Injection, teclistamab-cqyv, 0.5 mg

References:

1. Tecvayli (teclistamab-cqyv) [package insert]. Horsham, PA: Janssen Biotech Inc.; October 2022.
2. National Comprehensive Cancer Network (NCCN) Guidelines: Multiple Myeloma. Version 3.2023.
3. Dose Escalation Study of Teclistamab, a Humanized BCMA*CD3 Bispecific Antibody, in Participants With Relapsed or Refractory Multiple Myeloma (MajesTEC-1). ClinicalTrials.gov Identifier: NCT03145181. Accessed online December 28, 2022 at https://clinicaltrials.gov/ct2/show/NCT03145181.
4. A Study of Teclistamab in Participants With Relapsed or Refractory Multiple Myeloma (MajesTEC-1). ClinicalTrials.gov Identifier: NCT04557098. Accessed online December 28, 2022 at https://clinicaltrials.gov/ct2/show/NCT04557098.
5. Moreau P, et al. Teclistamab in relapsed or refractory multiple myeloma. N Engl J Med. 2022;387(6):495–505. doi:10.1056/NEJMoa2203478.

Approval And Revision History

January 18, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

February 14, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Originally approved February 14, 2023 by P&T and January 18, 2023 by MPAC committees effective April 1, 2023
- Coding update per HCPCS level II quarterly release. Effective date July 1, 2023, the following HCPCS code has been added: J9380 replacing C9148

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.